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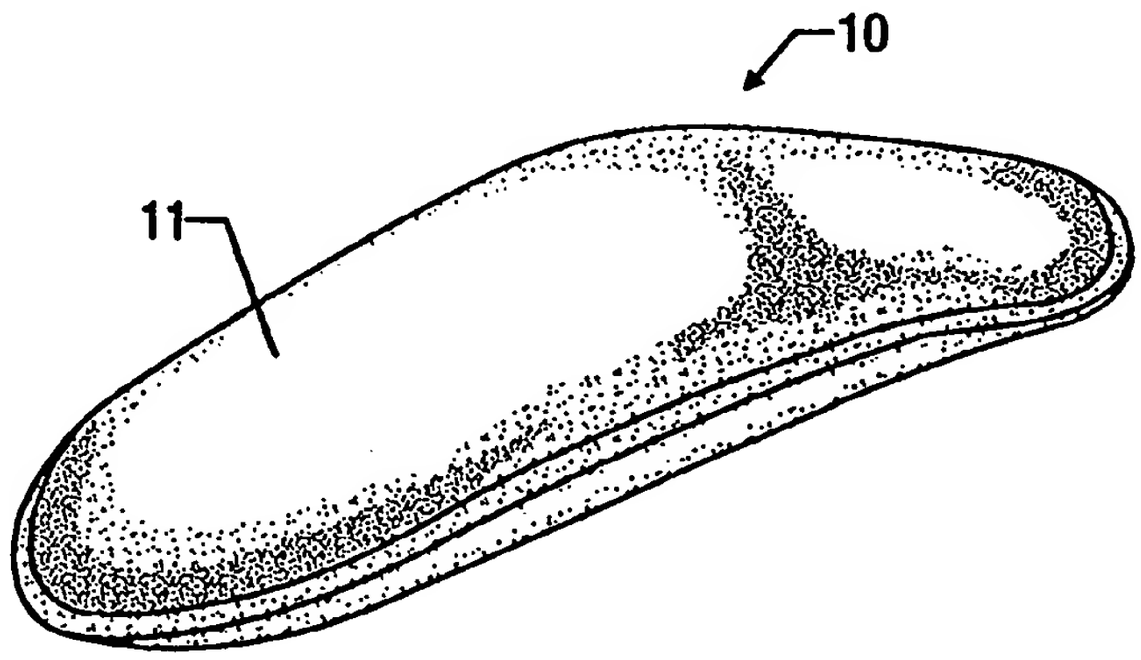
(54) Title: ORTHOTIC SHOE INSERT AND METHOD OF MAKING SUCH AN INSERT

(57) Abstract

A method of making a semirigid orthotic insert for a shoe comprising the steps of making a shell having an imprint of the user's foot on its top surface. Then when the shell is placed in the shoe in which it is to be used, the foot is positioned so that the ankle and leg bones are in the preferred alignment. Then the space created between the heel portion of the bottom of the shell and the sole of the shoe is filled with appropriate material to support the shell in the preferred position. This in effect tilts the shell, which is semirigid so that there is a space created between the ball portion of the shell and the sole of the shoe. This space is then filled with an appropriate support material so that when the shell is in the shoe it supports the foot in its preferred subtalar neutral position.



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ORTHOTIC SHOE INSERT AND METHOD OF MAKING SUCH AN INSERT

This invention relates to Orthopedic Shoe Inserts and to a method of making such an insert. In particular this invention relates to an orthopedic shoe insert which is manufactured to maintain the foot in its natural subtalar neutral position and correct midtarsal joint alignment when the insert is positioned within a shoe to be worn by the user.

A functional foot orthosis or orthopedic shoe insert is a device placed inside a shoe and worn underneath the foot. A functional foot orthosis is used to synchronize the mechanics of the lower limb by holding the joints of the foot in as near to their optimal functioning position as possible. Because the optimum functioning position of the joints of almost all feet end up creating an angle between the weight bearing surface of the foot and the ground, disadvantageous compensatory movement out of that optimum joint alignment normally occurs on weight bearing. Functional orthoses assist in controlling foot geometry and force direction by reducing the need for muscles to compensate for joints not staying in their more stable positions. To provide normal motion while bearing weight, joints of the foot must move only within their normal planes of motion and only to a limited extent. Ideally, at mid-stance, both the subtalar and midtarsal joints are in their neutral position, that is in full congruency, with the heel and ball of the foot being parallel to the weight bearing surface. If when the subtalar and midtarsal joints are in their proper alignment, the heel and/or ball is not parallel to the weight bearing surface, then it is the purpose of a functional orthosis to bring the surface up to the foot. The primary objective of functional orthoses is to control position and motion of the foot, thus compensatory hypermobility can be reduced and kinetic joint stability can be established during stance phase activity of the foot with a minimum expenditure of muscle energy.

A functional orthotic shoe insert is composed of three parts: a shell covering the plantar portion of the foot; a rearfoot support which aligns the subtalar joint properly and supports and maintains the correct angle of the heel of the foot to the ground; and a forefoot

support which aligns the midtarsal joint correctly and supports and maintains the correct angle of the ball of the foot to the ground.

The shell is a semirigid material that is form fitted to the planter foot, or positive cast of such, as it is held in a non-weight bearing position such that the subtalar joint is in its neutral or most congruent alignment and the midtarsal joint is in its maximally prorated position. This position allows the foot to operate throughout its functional purpose with the best joint alignment possible while allowing for adequate adaptive pronation. The shell cannot provide this on its own however.

Posting is the means of supporting and maintaining the correct angulation of the planter surface of the orthosis shell at its two weight bearing surfaces, the heel and the ball of the foot. The posting angles are needed to establish and maintain the angle that the planter foot makes to the ground as the subtalar joint is in its neutral position and the midtarsal joint is correctly aligned. These angles are indicative of the correct mid-stance relationship of the foot to the ground, i.e. they do not indicate the relaxed compensated stance the user may assume on weight bearing which can be altered by any one of many possible deformities that may be present. Posting aims to hold the foot in as near to its correct mid-stance relationship as possible and thus to allow more normal articulated function from this position. By controlling the movement in the subtalar joint and supporting the forefoot portion of the shell in its correct angular position relative to horizontal, the need for compensatory movement is removed and the limb is able to function normally.

The rearfoot post corrects the anatomical and evolutionary tendency of the heel to be non-perpendicular to the ground by angling the bottom of shell relative to the horizontal. This allows full-width heel weight bearing while at the same time limiting the subtalar joints' function within a much smaller range on either side of correct neutral position. The rearfoot support maintains the shell at an angle which is a combination of tibial angulation and calcaneal angulation when the subtalar joint is in congruence. The statistical incidence of

either tibial valgum or calcaneal valgus when in subtalar neutral position is inconsequential and so some degree of net rearfoot varus angulation can be assumed.

The forefoot post is the means of supporting and maintaining the shell in the correct angle required to support the ball of the foot in its correct angular relationship with the rearfoot post when the subtalar joint is in its neutral position and the midtarsal joint is fully prorated. The forefoot angle is the combined total of the rearfoot angle and the midtarsal joint angle. The forefoot angle is measured from a horizontal and is the "pure" angle to which the forefoot can be posted. The talonavicular and the calcaneocuboid joints together form the midtarsal joint.

Forefoot angulation is both more variable and more complex than that of the rearfoot, as the movement of the defining midtarsal joint occurs around two axis which are often opposed to each other. Additionally, deformities often act on the midfoot and forefoot which further complicates its compensatory action. The starting point, however, for a correct forefoot post is that which aligns the shell at the ball of the foot relative to horizontal with the rearfoot stabilized.

As previously discussed, a correctly molded shell, aligned to the 3-dimensional shape of the planter surface of the foot as that foot is held in the position of subtalar neutral and midtarsal maximally prorated joint alignment, will by definition reflect the biomechanically correct angular relationship of the forefoot and the rearfoot in the frontal plane. If that relationship is accurately "captured" in the shell then the correct forefoot angle to the ground will be determined once the rearfoot is fixed, posted or stabilized in a given location. The forefoot portion of the shell is then automatically angled correctly, relative to the rearfoot. It only remains to stabilize the forefoot portion of the shell at the proper angle so that the entire device, and foot, does not tilt or roll in the frontal plane as weight is shifted proximally or distally.

It is the primary object of this invention that by filling the space formed by the aforementioned angle of the forefoot of the shell and the flat horizontal with any appropriate type of support material, or bending the most raised portion of the shell to the ground, a biomechanically correct forefoot support has been created or formed.

Background Art

In making prior art orthopedic shoe inserts, an initial mold for the foot is made when the planter portion of the foot is held in the subtalar neutral position. This is the correct alignment for the joints of the foot and provides the most stability and the least amount of stress to the foot, ankle, and leg. U.S. Patents 4,597,196 and 4,718,179 contained detailed descriptions of a foot mold and an orthopedic shoe insert. There are a large number of patents that address the potential problem of adjusting the shoe insert prior to positioning in a shoe. These patents, however, are mainly directed to adjusting the insert in the area of the heel to have it fit more snugly in the shoe and reduce the discomfort of the user of the insert. For examples see U.S. patents 4,654,948 and 4,962,593. In addition, U.S. patent 5,327,664 teaches the adjustment of the shoe insert near the ball of the foot.

The problem with the teachings of the prior art is that these adjustments are made independently of each other and do not take into account the change in the alignment of the foot and/or concurrent change of the geometry of the planter surface of the foot when the angular position of the shell is changed or adjusted relative to the sole of the shoe, in relation to the unchanging geometry at the insole. When the heel portion of the shell is adjusted, or posted, without the shell reflecting subtalar neutral position, the sometimes large variation in geometry then created between the planter surface of the foot and the upper surface of the shell will create much stress on the muscles and the bones supporting that portion of the foot. The shoe insert of this invention takes into account and reflects the changed or corrected foot alignment and its planter geometry when the angular correction is made to the planter surface of the insole shell. In other words, if the orthosis is going to have corrected angulation applied to it, the shape of the shell should reflect the shape of the foot when it is held in the

subtalar neutral position. It should be noted that fabricating a shell with the foot in an attempted subtalar neutral position as taught in U.S. patents 4,597,196 and 4,718,179 without providing the necessary corrective angle when inserting the shell in a shoe also puts uneven pressure on the foot resulting in unnecessary stress.

The approach of this invention is unique in that it addresses all three parts of a functional orthosis and does so in an interdependent fashion, unlike any of the previous art which may address one or perhaps two of the three, and not in the interdependent manner necessary.

Therefore, it the object of this invention to provide a new and improved orthopedic shoe insert.

Another object of this invention is to provide a new and improved orthopedic shoe insert which maintains the foot in the subtalar neutral and midtarsal maximally prorated position when the insert is positioned within the shoe. Another object of this invention is to provide a new and improved method of providing an orthopedic shoe insert which minimizes the stress on the foot, ankle, and leg.

Description of the Drawings

This invention is illustrated in connection with an orthotic shoe insert in which:

Figure 1 is a top view of the insert of this invention.

Figure 2 is a bottom view of the insert of Figure 1.

Figure 3 is a side elevation view of the medial side of the insert of Figure 1.

Figure 4 is a cross section view taken along the line 4-4 of Figure 3.

Figure 5 is a cross section view taken along the line 5-5 of Figure 3.

Figure 6 is a view showing the angle extending from the point of contact between the insert and the sole of the shoe at the heel portion of the insert

Figure 7 is a view showing the angle extending from the point of contact between the insert and the sole of the shoe at the ball portion of the insert.

Figure 8 is a side view of the medial side of an insert of this invention with the support portion beneath the heel portion of the insert being formed integral with the insert. Figure 9 is a cross section view taken along the line 9-9 of Figure 8. The first step in making the novel shoe insert of this invention is to make a mold of the foot in the subtalar neutral position with the midtarsal joint maximally prorated. From this mold is made a semirigid shell 10 preferably of uniform thickness which resembles the bottom of the foot in the preferred neutral position, or in alternate method the mold itself can be the shell. The top 11 of the shell 10 contains an impression of the bottom of the foot correctly aligned in its subtalar neutral position. The shell 10 can be made of any appropriate material such as a thermoplastic material sold by DuPont under the trademark Surlyn. When this material is set after heating and receiving the impression of a foot, it is semirigid and can maintain the foot impression on its upper surface. The bottom surface 12 of the shell can be flat to facilitate making the angular adjustments to the shell relative to the insole of the shoe in which the shell is going to be used.

When the shell 10 is positioned within a shoe it has to be adjusted or angled to align the foot in the preferred subtalar neutral position of alignment. When this is done, there is a slight angle formed between the bottom of the shell 10 and the sole 14 of the shoe as shown in Figures 6 and 7. The space between the bottom surface of the shell 10 at the heel 15 and the horizontal surface of the sole of the shoe is filled with appropriate support material 16 to

maintain the shell in the proper position to align the leg and the heel. The space may be filled with any appropriate support material such as shims, wedges, or thermosetting material attached to the bottom of the shell so that when the shell is placed within the shoe and pressure is applied, the heel portion of the shell remains in position to place the foot in the preferred subtalar neutral position. In an alternate method the support material or wedge on the bottom of the shell can be made integral with the shell when it is initially formed as shown in Figure 8.

When the heel portion of the insert has been properly positioned within the shoe, the bottom of the shell 10 at the ball of the foot 18, usually forms an angle with the horizontal plane of the sole of the shoe 14 on which the shell is positioned. Such an angle is illustrated in Figure 7. This angle is formed unless the angle at the ball of the foot, when the midtarsal joint is fully prorated, is exactly opposite and equal to that of the rearfoot angulation. Then net sum or difference will be reflected because the shell is semirigid. Even if a given foot presents no midtarsal joint angulation, the forefoot will still reflect the amount of angulation at the rearfoot since forefoot angulation equals the sum of the rearfoot and the midtarsal joint angles. The space between the bottom of the ball portion 18 of the shell 10 and the sole of the shoe 14 is then filled with shims, wedges, or other support material 16 attached to the bottom of the shell to maintain the relationship of the position of the ball of the foot to the heel as the midtarsal joint is in its preferred maximally prorated position as captured by the mold of the foot when the shell was formed. In this way, when the insert is put in the shoe, and weight is applied on the foot the foot will remain in the preferred subtalar and midtarsal positions.

The significance of making the shoe insert in accordance with this method is to keep the subtalar joint in its preferred subtalar neutral position and the midtarsal joint in its preferred maximally prorated position when the foot is placed in the shoe. The use of this insert will minimize the stress on the bony structure of the foot as well as the muscles supporting the foot which are stressed when the foot is not in the preferred subtalar neutral

position. This invention distinguishes from the prior art by taking into account the fact that adjustments or angulation to the ball portions of the shoe insert are necessary if the rear heel portion of the shoe insert is adjusted or angled to better control subtalar joint motion, moreover, the precise and correct relationship between such angles are uniquely reflected in this invention. After adjustment is made to the heel portion of the insert relative to the sole of the shoe, the forepart of the insert may be twisted upon bearing weight since the shell is semirigid. Therefore, means must be provided to support the ball portion of the shell relative to the sole of the shoe to keep the insert in the preferred maximally pronated midtarsal joint position, at the same time that the subtalar joint motion is being controlled when the wearer applies pressure to the shoe.

In operation after the shell has been formed by taking an impression of the foot the support material 16 at the heel portion of the shell would be in one preferred method in the form of a wedge that can be attached to the bottom of the shell. The support beneath the shell can also be provided by adding material such as thermosetting material to the bottom of the shell in the heel area or by providing a post which can be fitted to the bottom of the shell before inserting it into the shoe. As an alternative in commercial operation a shell can have a predetermined angle molded into the bottom of the heel portion of the shell. In another form, wedge supports of various angulations can be provided to allow more customized angulation of the rearfoot to accommodate varying requirement of users. In such an application it is desirable to make the bottom of the shell at the heel and ball portions flat to facilitate the use of conventional wedge shaped inserts to fill the space between the shell and the sole of the shoe.

When the support is applied beneath the heel portion of the shell, the ball portion of the shell is twisted or tilted relative to the sole of the shoe. The angle between the shell and the sole of the shoe near the ball portion 18 can occur on either side of the shell and can be of any magnitude. Therefore, after the adjustment to the heel portion of the shell is made to fit the insert in the shoe the space between the bottom of the shell and the sole of the shoe near

the ball of the foot must be filled with an appropriate support material, such as a thermosetting material or wedges, to physically support the shell and allow it to continue reflecting the correct midtarsal alignment of the foot and leg while in the preferred subtalar neutral position when the foot is inserted into the shoe and pressure is applied.

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It will be apparent to those skilled in the art that various modifications and changes can be made within the spirit and scope of the appended claims.

Claims:

1. A method of making an orthotic insert adapted to be placed in an article of footwear comprising the steps of:

(a) preparing a shell of a semirigid material, the top of said shell having the imprint of the bottom of a potential user's foot in its preferred subtalar neutral and midtarsal maximally prorated alignment,

(b) applying support material to the bottom of the heel portion of said shell to align said shell within an article of footwear so that the heel, subtalar joint, and leg of the user are in the preferred aligned position.

2. A method of making an orthotic insert adapted to be placed in an article of footwear comprising the steps of:

(a) preparing a shell of a semirigid material, the top of said shell having the imprint of the bottom of a potential user's foot in its preferred subtalar neutral and midtarsal maximally prorated alignment,

(b) applying support material to the bottom of said heel portion of said shell to align said shell within an article of footwear so that the heel, subtalar joint, and leg of the user are in the preferred aligned position, and;

(c) attaching support material to the bottom of the shell beneath the ball portion of the shell to hold the shell in the preferred position.

3. A shoe insert comprising:

a shell of semirigid material having an impression of the bottom of the foot of an intended user on its top,

said foot impression being made when the foot is in the preferred subtalar neutral position and maximally prorated midtarsal joint alignment of the intended user,

a support between said shell and the sole of the shoe at the heel portion of said shell to place the foot into a preferred rearfoot alignment with the leg of the user and;

a support between said shell at the ball portion of said shell and said sole to maintain said shell in the preferred midtarsal aligned position.

4. The method of Claim 2 in which said shell is made of material having a substantially uniform thickness.

5. The method of Claim 2 in which the bottom of said shell is made flat.

6. The insert of Claim 3 in which said shell is made of a thermosetting material.

7. The method of Claim 2 in which said support material at the heel portion is formed integral with said shell.

8. The method of Claim 7 in which said support material causes said shell to be angled at approximately 6 degrees relative to the sole of said footwear.

9. The insert of Claim 3 in which said supports are wedge shaped.

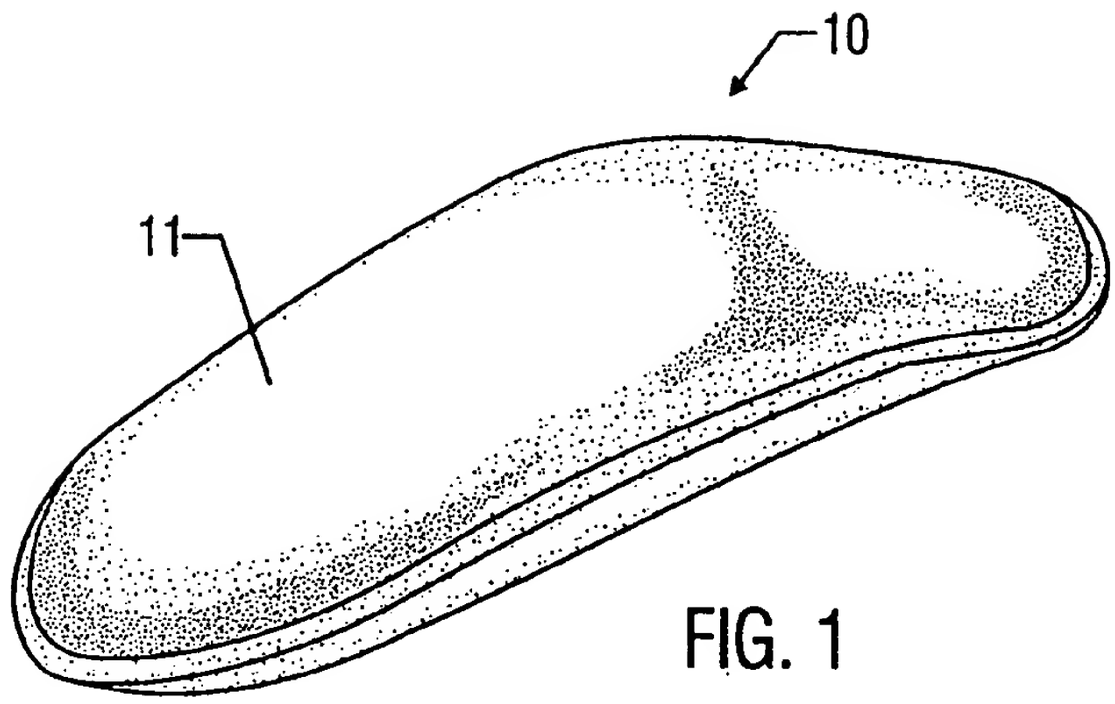

FIG. 1

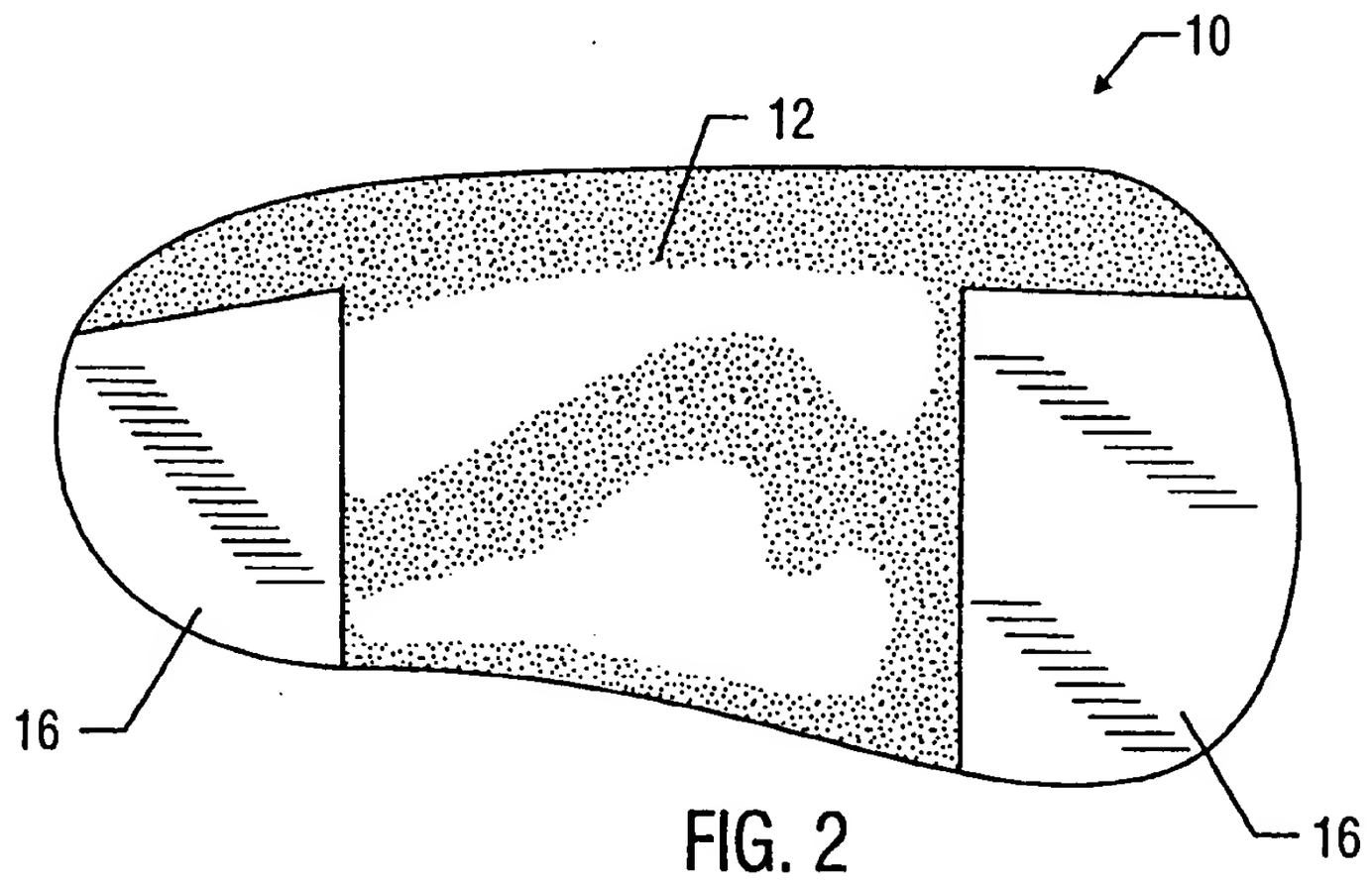

FIG. 2

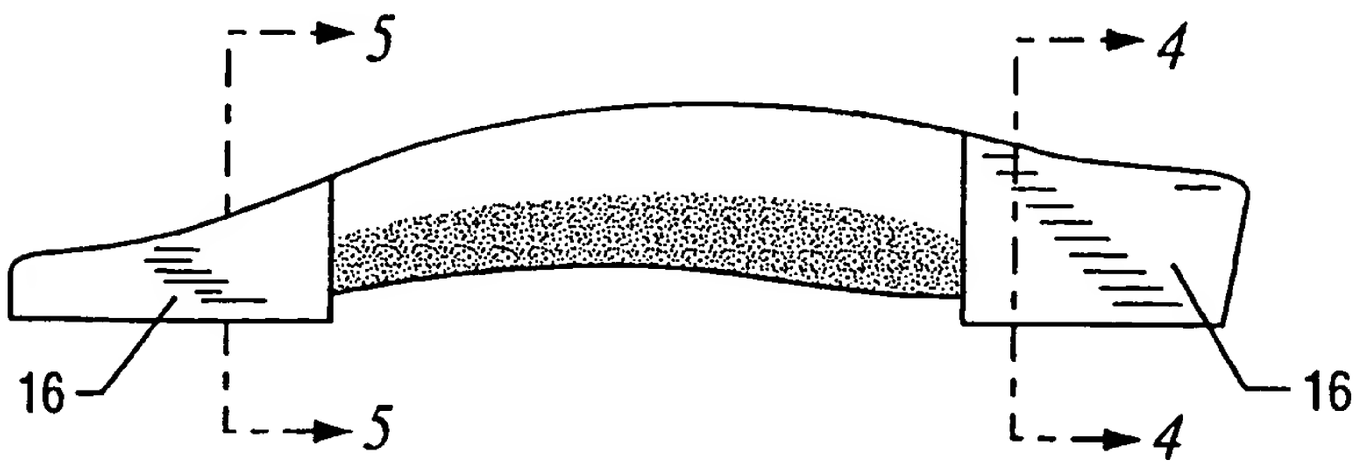

FIG. 3

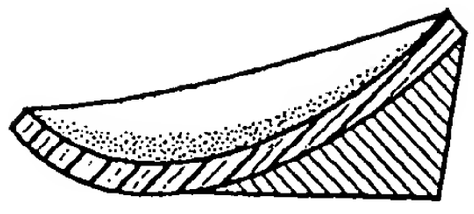

FIG. 4

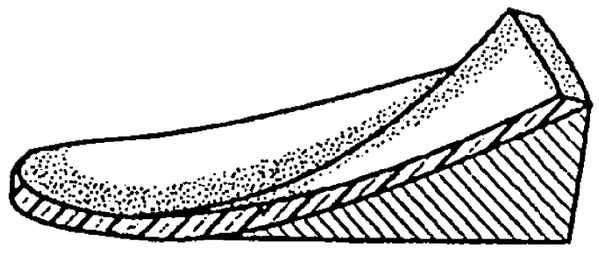

FIG. 5

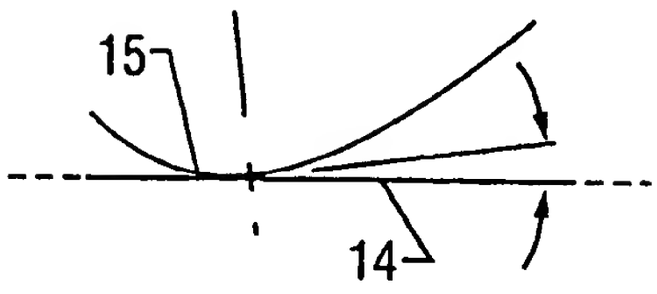

FIG. 6

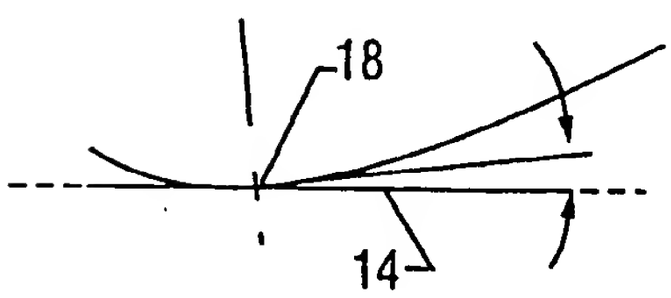

FIG. 7

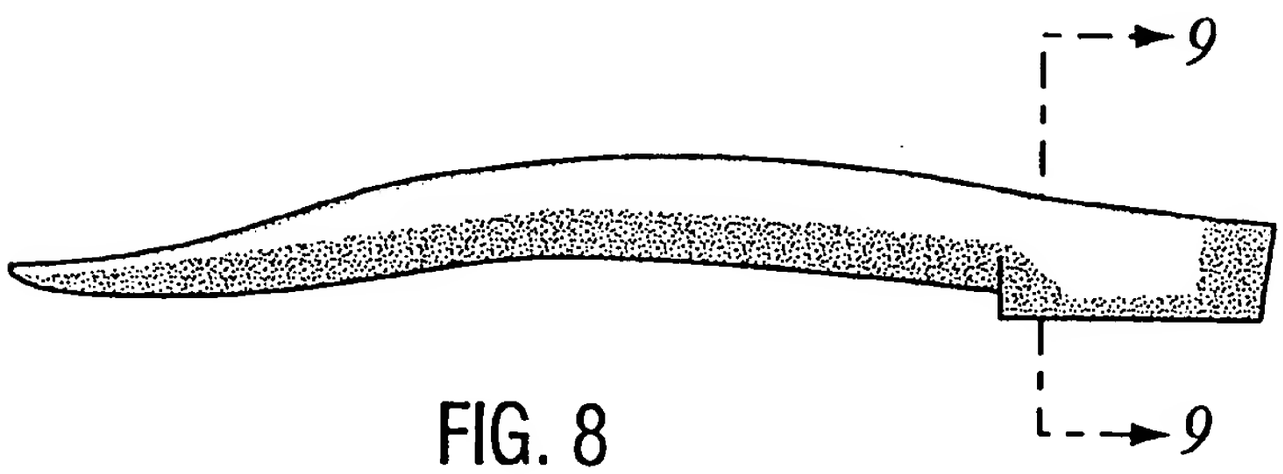

FIG. 8

FIG. 9

INTERNATIONAL SEARCH REPORT

Intern: al Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A43B7/28

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A43B

Documentation searched other than minimumdocumentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 592 282 A (M. DENIS) 3 July 1987 see the whole document ---	1-3
A	US 4 868 945 A (J. DEBETTIGNIES) 26 September 1989 see the whole document ---	1-3
A	DE 30 41 713 A (E. THIEL) 9 June 1982 see the whole document ---	1-3
A	WO 95 31161 A (R. CHARLES) 23 November 1995 see the whole document ---	1-3
A	WO 94 14391 A (K. YERRATT) 7 July 1994 cited in the application see the whole document ---	1-3

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

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